

**REMARKS**

Claims 25-36 are all the claims pending in the application. The Examiner has rejected claims 25-27, 29-31, and 33-35, and has objected to claims 28, 32, and 36.

Claim 28 is rewritten in independent form. No new matter has been added.

**I. Claim Objections**

The Examiner objects to claims 28, 32, and 36 for depending from rejected claims.

Claim 28 has been rewritten in independent form. Therefore, claims 28, 32, and 36 no longer depend from rejected claims, and accordingly, Applicants respectfully request that this objection be withdrawn.

**II. Rejections Under Section 102(e)**

The Examiner rejects claims 25-27, 29-31, and 33-35 under 35 U.S.C. § 102(e) as being anticipated by US Patent No. 5,974,164 to Chee. The Examiner states that Chee teaches all the elements of independent claim 25 which are generally, (1) a first detection means for detecting a first labeling substance, (2) a second detection means for detecting a second labeling substance, and (3) an analyzing means for measuring the quantities of both first and second labeling substances. The Examiner further states that a first detection means, a second detection means, and an analyzing means taught by Chee have the ability to perform the functions of the respective elements of claim 25.

### **III. Response Filed October 22, 2003**

In the previously filed Response Applicants asserted that Chee does not anticipate the claimed invention because the apparatus of claim 25 is both structurally and functionally distinct from that taught by Chee. The substance of Applicants' previously filed response appears below.

(1) In Chee, the first and second labeling substances are bound to separate samples that do not hybridize to each other, but hybridize separately to a third, unlabeled member (see Chee column 25, lines 4-6). In the instant application, the first and second labeling substances are bound to separate samples that bind, i.e. hybridize, to each other, and there is no third unlabeled member. Therefore, the instant invention and that taught by Chee are structurally distinct.

(2) In Chee, two separate samples are labeled, combined, and hybridized to a third member or probe. Chee thereby allows the experimenter to reduce variations between two samples since the samples underwent identical processing steps (see Chee column 24, lines 38-41). However, in the present application, the first labeled sample is disposed on a test piece, i.e. chip, and the second labeled sample is bound, i.e. hybridized, to the first labeled sample. The experimenter can therefore correct the signal from the second labeled sample at each position based on the amount of the first labeled sample disposed at that position. Therefore, the detection means of the instant invention do not allow correction between different experimental samples, as in Chee, but allow for correction within a single experimental sample. Therefore, the detection means of the instant application and those taught by Chee are functionally distinct.

(3) In Chee, the analyzing means does not correct the level of the second signal based on the level of the first signal, as in the present invention. The analyzing means in Chee merely

plots the level of the two signals on a graph, separately, and for each position on the chip. Where signals are the same, the lines will overlap; where the signals are different, they won't (see Chee, Figure 14A). Since Chee does not teach correcting the level of one signal based on the level of another signal, the analyzing means of the instant invention must be both structurally and functionally distinct from the analyzing means taught by Chee.

### **III. Advisory Action of January 22, 2004**

The Examiner states that the proposed amendments filed on October 22, 2003 have been fully considered but were not been entered because they were not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Specifically, the Examiner contends: (1) that since the specification does not specially define a first detection means and a second detection means, and since the specification and Chee teach the same means that is directed to the same function, the detection means of the instant application and those taught by Chee are not functionally distinct, and (2) since the specification does not specially define an analyzing means, and since the specification and Chee have the same means that is directed to the same function, the analyzing means of the instant application and the analyzing means taught by Chee are not structurally and functionally distinct.

### **IV. Response to Examiner's Comments**

Applicants do not agree with the Examiner's comments set forth in the January 22, 2004 Advisory Action, and provide the following explanation to supplement the previously filed comments (provided herein above).

Applicants assert that the invention of the present claims and the apparatus disclosed by Chee are structurally and functionally distinct. The Examiner's comments appear to separate the elements of the claim and analyze them independently and without regard to the recited limitations.

First, the presently claimed apparatus is not taught by Chee, and the apparatus of Chee cannot perform the function of the present invention. Claim 25 recites an apparatus where the specific binding substances (which are labeled by the first labeling substance and detected by the first detection means) are disposed on the test piece. In addition, claim 25 recites an apparatus where the organism-originated substance (labeled by the second labeling substance and detected by the second detection means) hybridizes to the specific binding substances (where complementary sequences are present). Chee does not disclose any labeled member disposed on a test piece, and Chee does not show two labeled binding substances that hybridize to each other.

The fact that the present apparatus and that of Chee have different structures is a consequence of the very different functions they are designed to perform. The present apparatus allows for the investigator to control within an experiment by correcting for different levels of the specific binding substance disposed at each position on the test piece. Chee, on the other hand, allows the investigator to control between different experimental samples (samples to be hybridized to unlabeled polynucleotides on a chip) by pooling the sample processing steps.

Therefore, since the present invention and the apparatus of Chee are structurally and functionally distinct, Chee does not anticipate the claimed invention.

Second, claim 25 recites an analyzing means for measuring a quantity of said organism-originated substance bound to said specific binding substance, based on the detected level of said second labeling signal, corrected for the detected level of said first labeling signal. Chee does not teach an analyzing means with these limitations. The scanning means of Chee (cited by the Examiner in Col. 16, first paragraph) does not correct the value of one signal based on the detected level of another. Since Chee does not teach the elements of the present invention, together with the recited limitations, Chee does not anticipate the present invention.

Applicants respectfully assert that the invention as a whole is structurally and functionally distinct from the apparatus of Chee, as Chee does not teach all of the elements and limitations of independent claim 25. Therefore, Applicants assert that Chee does not anticipate the claimed invention, and accordingly Applicants respectfully request that this rejection be withdrawn.

## **V. Conclusion**

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

Amendment Under 37 C.F.R. § 1.114(c)  
U.S. Appln. No.: 09/461,308

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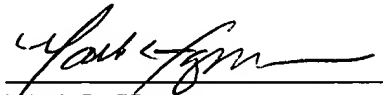
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**23373**

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